promote Suboxone in "off label" dosages (in excess of 24 mg per day) and uses (induction, during pregnancy and for pain) and to support Reckitt's false claims that Suboxone film was safer and less divertible. These ruses included: payments for "lunch and learns", mentorships, speaker programs, "teach the rep" programs, managed care presentations, and presentations to officials for state Medicaid agencies and state legislatures. Such conduct was in violation of the False Claims Act and the Anti-Kickback statute, 42 U.S.C. §1320a-7b.

viii. Defendants' sales representatives and TA's routinely and unlawfully distributed physician pricing schedules, referrals and dispensed advice to physicians on how to start and grow Suboxone-based practices and provided other services of value to physicians in order to induce them to prescribe Suboxone and Subutex in violation of the False Claims Act and the Anti-Kickback statute, 42 U.S.C. §1320a-7b.

ix. Defendants unlawfully gave physicians services and things of value in return for their prescribing Suboxone and Subutex through its "Here to Help" program in violation of the False Claims Act and the Anti-Kickback statute, 42 U.S.C. §1320a-7b.

x. Defendants unlawfully paid kickbacks to state Medicaid officials in order to obtain exclusive status on state formularies and to destroy competition in violation of the following laws and regulations: the Anti-Kickback Statute, 42 U.S.C. §1320a-7b; the regulatory "safe harbor" guidance provided at 42 CFR §1001.952(h); and the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Federal Register Vol. 68, No. 86, pp. 23734-23735 (May 5, 2003) ("2003 OIG Guidance").

xi. Defendants conspired with TA's other physicians and other persons to achieve the unlawful purposes set forth herein.

1) Marketing "Off Label" Dosages and Uses of Suboxone and Subutex

56. From 2004 until at least through 2013, Defendants' executives, TA's and sales representatives actively and unlawfully marketed and promoted "off label" dosages of Suboxone/Subutex in excess of 24 mg per patient per day to physicians so that these physicians would, in turn, prescribe these dosages to their patients. The maximum daily dosage/use approved by the FDA and/or indicated by the Package Insert was at the time, and still is today, 24 mg per day. All extant studies indicate that because of buprenorphine's "ceiling effect," daily dosages above 16 mg per day generally have no additional therapeutic benefits or use for patients.

57. Relator has personal knowledge that RBP's Vice President of Sales, Adrian Norton[4], was aware of and sanctioned the aggressive marketing and promoting of Suboxone and Subutex in dosages in excess of 24 mg per patient per day. RBP's and now Indivior's Zone Directors, and in particular Richard Powers, directed and continue to direct the Area Sales Managers to aggressively market and promote Suboxone and Subutex in dosages in excess of 24 mg per patient per day and directed their sales representatives to do the same.

58. To support and encourage sales representatives to market dosages over 24 mg per day, Defendants presented PowerPoint training programs promoting daily Suboxone and Subutex dosages of over 24 mg. While it is unknown to the Relator exactly how many times this PowerPoint presentation had been presented nationally, it was used on several occasions in regions throughout the United States to persuade sales representatives to market, promote and encourage physicians to prescribe Suboxone and Subutex in dosages above 24 mg per day.

[4] It is unknown whether Adrian Norton is still employed by Indivior, however, at the time Indivior was spun off from RBG and RBH the entire executive team of RBP, including Norton, remained as Indivior's executives.

59. In addition, Defendants' TA's were instructed to promote doses of Suboxone and Subutex in excess of 24 mg per patient per day to other physicians, health care personnel and state agencies, and did, in fact, promote the use of both drugs in dosages over 24 mg per day throughout the United States.

60. Defendants' Zone Director and National Sales Director, Richard Powers, along with Area Business Directors and Area Business Managers, including but not limited to, Jeff Bodenburg, Jason Boehmer, Rosemarie Paulus, Michael Himple, Laurie Kyle and Michael Bruno, exhorted their sales representatives and TA's to increase volume on Suboxone and Subutex sales. These executives openly encouraged sales representatives to persuade physicians that dosages in excess of 24 mg per day were beneficial to many patients. Such promotion was done by utilizing information from misleading "detail pieces," such as their Product Monograph, and by verbally suggesting that dosing over 24 mg per day was effective. These executives further unlawfully marketed Suboxone and Subutex for the off label use of pain to circumvent the maximum allowed dosage, cover up the unlawful prescription dosage level and/or bypass the constrictions of DATA 2000. Some of the sales representatives personally known to the Relator as having made misleading representations are Ana Farr, Scott Daniel, Jaime Neil, Joe Hall, Clint Gagnon, Andie Hall, Mary Bashkar, Teri Turconi, Melanie Miller, Mathew Holland, Scott Norman, Gina Reed, Stephanie Galcia, Lori Davis, Lori Eaton and managed care specialists Paul Bragoli, Keith Lockwood, Juan Tripp and Sam Moffett.

61. The effort by Defendants' executives, sales representatives and TA's to market Suboxone and Subutex for use in dosages exceeding 24 mg per day was coordinated and well known to senior executives including those identified in the paragraphs above. In fact, in the

summer of 2013, while in her office, Brandi Duso, the Compliance Officer for RBP, admitted to Relator that evidence of the high dosage marketing practice was "overwhelming."

62. The State and Federal Payors paid significant sums because of prescriptions issued as a result of Defendants' unlawful efforts that otherwise would not have been paid. By 2010, state Medicaid programs, legislators and others began expressing concern about the high dosages (and the corresponding government payments for these higher dosages) as well as the diversion and misuse of the drug that was occurring. A few states began to limit the dosage levels for which Medicaid payment would be allowed. Defendants' employees nevertheless continued to market the drug at higher dosage levels which encouraged physicians, at times, to write two prescriptions, one paid for by Medicaid and another paid for in cash.

63. Defendants' employees knew that, as a consequence of prescribing higher dosages, many patients would divert the tablets or film for resale and misuse by the public. Such diversion and misuse by the public became pandemic and a root cause of further addiction and crime.

64. Some of Defendants' sales representatives complained to their Area Managers that it was an "off label" practice to market Suboxone and Subutex in the manner described in the preceding paragraphs. These representatives were dissuaded from taking any further action or were fired.

65. In June 2010, Relator was present at a Kentucky Pharmacy Association meeting in Louisville, Kentucky. Reckitt sales representative, Jamie Neal, was also there and was operating Defendants' promotion booth for Suboxone. She openly promoted Suboxone in dosages above 24 mg per day. When Neil was confronted by Relator about her marketing statements concerning the dosages, Neil stated, "You don't understand, I must keep my volume

up or my boss [Jeff Bodenburg] will fire me." Relator confirmed through other sources that Bodenburg instructed sales representatives to promote dosages above 24 mg.

66. In the summer of 2010, Dr. Thomas Badgett, Kentucky Medicaid Medical Director, convened a meeting to discuss serious concerns involving the high volume and dosages of Suboxone being paid by Medicaid. Other concerns involving public safety issues surrounding the misuse of the drug were discussed. Dr. Badgett, Van Ingram (Kentucky Office of Drug Policy), Michelle Flowers (Kentucky State Behavioral Health and Substance Abuse) and Relator were in attendance.

67. Dr. Badgett presented Relator with data showing an astounding number of high dosage prescriptions of Suboxone. These data included prescriptions over 24 mg and up to 108 mg per patient per day and also included physicians who were prescribing to more than the 100 patient limit allowed by Data 2000. While this was consistent with what Relator was hearing in other states, Kentucky was more severe. Dr. Badgett expressed great concern over the misuse and abuse of Suboxone. He questioned whether Suboxone was being used for treatment or whether it was just another opioid to be abused like OxyContin.

68. The evening after that meeting, Relator emailed her immediate boss, David Byram, along with Vickie Seeger, Richard Powers, and Adrian Norton about Dr. Badgett's concerns and her own concerns. She asserted that Defendants were intentionally marketing the large volumes and off label dosages of over 24 mgs per day per patient. She asserted that RBP was creating the environment for diversion and misuse. Relator cited specific examples of unlawful marketing and accused them of being fully knowledgeable of the ongoing abuse in the Appalachian area. She questioned how they could tout their concern for patient care with

Suboxone on one hand, yet still promote dosages in excess of 24 mgs per day per patient and support physicians who were over their Data 2000 limit.

69. The following morning Relator received a call from Byram and was told that her email was inappropriate and should not have been written. She was advised that Norton and Seeger were furious. When Relator asked what was untrue about the email, Byram admitted that it was all true but asserted that it should have been stated orally and not in writing.

70. Seeger also called Relator and assured her the Suboxone film was going to help with the diversion and pediatric exposure issues. Seeger admitted that she knew things were out of control and understood her concerns. Relator later learned that Seeger's representation of how the film would help curb the diversion problem was false and that Reckitt officials knew same was false. Dr. Ed Johnson, RBP's Medical Director, was privately stating that the film was not safer, was not less divertible, and not subject to less abuse as discussed *infra*.

71. Relator also received a response to her email from Norton. He directed her not to put anything in writing again concerning these matters. Relator's emails to Norton, Powers, Bodenburg, Seeger and Byram referencing these issues were removed by Defendants after her computer was turned over to RBP's IT department for a software update.

72. After Relator's email referenced in paragraph 68, above, Richard Powers set up a meeting in Indianapolis, Indiana, with Relator, Jeff Bodenburg, Jason Boehmer and a Reckitt Medical Associate. Powers started the meeting by suggesting that Relator was new to the company and did not understand the history of Reckitt and the marketplace of opioid addiction. Powers had Bodenburg and Boehmer attempt to indoctrinate Relator by explaining the history of Reckitt. She was advised that they knew about the diversion but diminished the concern by stating diversion was good as it led addicts to treatment. They also tried to convince Relator that

32 mg was an appropriate dosage. Relator challenged the appropriateness of the dosage. At times Bodenburg was angered and accused Relator of working against the team.

73. On September 16, 2010, a hearing of the Kentucky Medicaid Pharmacy and Therapeutics Committee was held in Frankfurt, Kentucky. Of major concern to the committee were the high dosages of Suboxone being prescribed. The committee was meeting, in part, to consider the necessity of a "pre-authorization" from Medicaid before Suboxone and Subutex could be prescribed. Dr. Badgett was present and reported that 33% of the Kentucky Medicaid population was on dosages of 32 mg per day per patient or more.

74. Two of Reckitt's TA's attended the meeting to argue against pre-authorization and supported dosages over 24 mgs. A committee member asked Dr. Stephen Lamb, one of the Reckitt TA's, if he had any interest in Reckitt, and Lamb responded that he attended the committee meeting on his own volition. Upon further questioning he admitted that he had been asked to attend the meeting by Jamie Neil, Defendants' sales representative. He did not disclose his status as a paid Reckitt TA. Relator questioned Dr. Lamb afterwards, and he again confirmed that he had been asked to attend by Neil.

75. Relator reported her concerns about Neil requesting that Lamb attend the meeting to David Byram and to Richard Powers. Relator was advised in an email from Byram to "leave it alone now."

76. Relator has personal knowledge of other sales representatives marketing off label dosages of Suboxone. One of the most successful was Joe Hall. His territory included Kentucky, Tennessee, and Southwest Virginia and his patient numbers using Suboxone were approximately 9000. When Relator asked him how he was so successful, he stated that you had to increase value to get bonuses at Reckitt. When a physician got to a hundred, he had to get them to write

dosages of over the 24 mg maximum dose. She asked him if this increased the rate of diversion, and he replied "absolutely". He further advised that his boss, Jeff Bodenburg, instructed him specifically to do what he was doing with respect to the excess dosaging.

77. As stated previously, the off label dosages were not only promoted by the sales representatives but also by Defendants' Treatment Advocates. One such TA was Dr. Bryan Wood. Dr. Wood and other TA's were paid by Defendants to go to other physicians' offices and promote the use of Suboxone for "off label" purposes. Dr. Wood discussed his practice's liberal use of dosages above 24 mg per day at the "lunch and learns" and similar forums where Defendants promoted and endorsed this practice as well as others.

78. On December 8, 2010, Dr. Wood reported in an email to Defendants' executives and sales representatives Derrick Hawkins, Terry Ragland, James Durham, Jaime Neil and the Relator that 40% of patient dosages at a large practice in Kentucky and Tennessee known as SelfRefind Physicians exceeded 24 mg per day in November of 2010. In this practice, 18.03% of their patients were taking 28 mg per day, 21.21% were taking 32 mg per day, and 1% were taking more than 32 mg per day. Dr. Wood stated to the Reckitt sales representatives and executives in the email, "[W]e will use it [the dosage data related above] as we move forward educating our physicians about appropriate dosing strategies, tapering strategies and comparisons among like providers (other SR physicians.) Thought you would want to know."

79. In addition to the above, Relator also has direct knowledge of Defendants maintaining a sales representative bonus structure known as the Sales Incentive Program ("SIP") pursuant to which sales representatives were paid on volume of Suboxone and Subutex prescribed thus encouraging and supporting the unlawful marketing. Defendants have maintained this program or a variation of it for many years.

80. Sales bonus volumes were not capped at individual prescription volumes of 24 mg per day but were paid on volumes exceeding the 24 mg limit as well. This provided an incentive to the sales representatives to market Suboxone and Subutex at higher levels so their sales volumes were high and, correspondingly, their bonuses were high.

81. In April 2013, at the Reckitt National Sales meeting in Florida, Brad Ashby, the manager of the SIP program, admitted to Relator that he knew that the marketing and sales of Suboxone at dosages over 24 mg per day was endemic from "New Orleans up the Appalachian Trail" and further admitted that he knew the SIP program was paying bonuses to the sales representatives which included volumes of the drug sold for prescription dosages over 24 mg per day. While at the meeting, Gay Green Cardin, a sales representative, also admitted to Relator that Area Business Manager Boehmer had instructed sales representatives to try and persuade physicians to dose at 32 mg and above per day per patient.

82. The use of Defendants' SIP program was a fundamentally different and more egregious bonus or incentive practice than those employed by other pharmaceutical companies. In the case of Defendants, Suboxone and Subutex were not indicated for dosages over 24 mg per day. Reckitt had the ability to easily determine if Suboxone was being prescribed by physicians in dosages higher than 24 mg per day, and in fact, maintained statistics on same. Despite being able to easily determine whether doctors were prescribing Suboxone off-label and restricting the SIP program bonuses only to those individual patient sales volumes at or below 24 mg per day, Defendants intentionally ignored this information and paid bonuses for sales volumes that included individual patient dosages higher than 24 mg per day. By the very nature of the SIP program, Defendants intentionally and knowingly encouraged and permitted the illegal dosage scheme and paid their employees bonuses for their success. This incentivizing system was one of

the engines that drove up the alarming dosage levels seen by state legislators and the state Medicaid agencies.

83. Defendants knowingly and unlawfully marketed and promoted the off label use of Suboxone in dosages greater than 24 mg per day to hundreds of physicians across the United States, including, but not limited to, those listed below:

PHYSICIANS	PRACTICE LOCATION
Herbert G.	Pennsylvania
Frank S.	Pennsylvania
William C.	Pennsylvania
David S.	Pennsylvania
Philip L.	Pennsylvania
Arthur D.	Pennsylvania
Mariano P.	Pennsylvania
Adid B.	Pennsylvania
Leo F.	Pennsylvania
Rallie M.	Kentucky
Piotr Z.	Kentucky
William F.	Kentucky
Clifford D.	Tennessee
Richard P.	Tennessee
Clary F.	Tennessee
Michael M.	Tennessee
Daniel P.	Tennessee
Arthur B.	Tennessee
MacK H.	Tennessee
Melvin L.	Tennessee
Timothy C.	Virginia
Joshua W.	Virginia
Tomas V	West Virginia

The full names and practice locations of the above physicians, as well as others, have been provided in Relator's disclosure of evidence.

84. In addition to the off label use described above, Defendants' executives, sales representatives and TA's, including many of those identified in paragraph 55 above, knowingly

and unlawfully promoted off label use of Suboxone tablets and film for use in induction, treatment of pain and during pregnancy when no such uses were indicated in the Package Insert.

85. Throughout her tenure with RBP, Relator attended numerous roundtables and other meetings where Defendants' TA's promoted off label uses of Suboxone and Subutex as to dosage, pain treatment, use during pregnancy and for induction to other physicians. These roundtables and meetings were also attended by sales representatives who did nothing to restrain the TA's when they presented to the physicians.

86. In 2013, Defendants' TA's and managed care representatives were given a national training presentation sponsored by Defendants which encouraged and sanctioned the prescription of Suboxone, in both tablet and film form, in dosages greater than 24 mg per day and for use in induction. The Relator has personally observed these training materials, is in possession of some of them and has disclosed same to the United States and the states identified herein. Dr. Jane Ruby, RBP's Medical Affairs Director and other Reckitt officials drafted these training materials.

87. An example of said training materials are attached hereto as **Exhibit D** and incorporated herein by this reference. A consultant drafted the training materials contained within **Exhibit D** for Defendants. The consultant was paid to draft these materials and then market Suboxone in accordance with the presentation contained therein.

88. Even as late as the summer of 2013, just before Relator left her employment with Defendants, she witnessed Dr. Bernd A. Wollschlaeger, one of Defendants' TA's, give a presentation to Virginia Premier, a managed Medicaid organization, in which he openly promoted Suboxone for treatment of pain, use during pregnancy and dosing over 24 mgs.

89. Such practice has continued even after Relator's departure as she witnessed Dr. Carl Sullivan, another TA, promote off label use of dosages over 24 mg per day, for use in treatment of pain, during pregnancy and for induction while at the West Virginia Medical Association meeting in September 2013.

90. Promotion of the use of Suboxone film and tablets for use in induction, pain management, during pregnancy and in doses well above those contemplated in the Package Inserts occurred throughout the United States.

91. Admissions related to certain of the above facts were audio-recorded and said recordings have been disclosed to the United States.

92. From approximately 2003 or 2004, Defendants' sales representatives promoted off-label uses of Suboxone tablets by encouraging physicians to review materials and information provided by an ostensibly independent patient advocacy organization known as The National Alliance of Advocates for Buprenorphine Treatment ("NAABT").

93. NAABT, through its website and other means, openly and aggressively promoted and continues to promote, the safety and efficacy of off-label uses of Suboxone and Subutex.

94. NAABT is not independent. The Defendants or certain of the Defendants have been the primary source of NAABT's funding for many years.

95. NAABT has maintained a *quid pro quo* arrangement with the Defendants where, in return for financial support provided by the Defendants, NAABT regularly and systematically published material on its website that openly advocated off-label marketing of Suboxone and Subutex.

96. Defendants used NAABT's appearance as an independent, non-profit entity in order to propagate materially false and misleading information about the Suboxone/Subutex

product line, was fundamentally inconsistent with the drug's FDA-approved package labeling and which directly contradicted the FDA's October 8, 2002 mandate that Defendants disseminate accurate educational material that complies with all manufacturers' labeling information.

97. NAABT's active concealment of its financial dependence upon the Defendants greatly improved their ability to market and promote Suboxone and Subutex. In reality, NAABT is nothing more than a *de facto* marketing arm of Defendants which operates to serve Defendants' unlawful marketing and promotional agenda.

98. The close relationship between NAABT and the Defendants has existed since the inception of NAABT in 2004. Some of the same addiction treatment advocates and clinical researchers who founded NAABT were intimately involved with RBP's securing of FDA approval for Suboxone tablets in 2002.

99. One specific example of the off-label promotion NAABT undertook is an article feature in NAABT's February, 2007, newsletter, Volume 3, No. 2, written by Richard Gracer, MD, and entitled "The Buprenorphine Effect on Depression." As its title suggests, this article advocates the use of Suboxone's primary ingredient, buprenorphine, as a safe, effective and appropriate treatment for depression.

100. Another article accessible on NAABT's website, "Challenges in Using Opioids to Treat Pain in Persons with Substance Use Disorders," written by Drs. Savage, Kirsh and Passik and published in the June, 2008 issue of *Addiction Science in Clinical Practice*, advocates using buprenorphine for pain management.

101. It is in the manner of the examples cited in the two preceding paragraphs that NAABT used its appearance of independence to engage in off-label marketing efforts on behalf of the Defendants that so plainly violate the False Claims Act and the state statutes cited herein.

2) Unlawful Kickback Schemes to Promote Sales of Suboxone/Subutex

a. The Anti-Kickback Statute

102. The Anti-Kickback Statute prohibits any payment, inducement or reward being conveyed to, or received from, any person for referring, recommending or arranging for the purchase of any pharmaceutical, medical service or medical device for which payment may be made under a federally funded healthcare program. 42 U.S.C. §1320a-7b(b).

103. Under the Anti-Kickback Statute, drug companies may not provide any services or remuneration, in cash or in kind, directly or indirectly, to induce the purchase, order or recommendation of drugs that are paid for by a federal healthcare program. *2003 OIG Guidance,* p. 23734. In addition to prohibiting outright bribes and rebate schemes, the statute also prohibits any provision of services, payments, or things of value any one purpose of which is to induce a physician to write additional prescriptions for a particular product, service or pharmaceutical. *Id.* Even if the provision of such value is also intended to compensate the recipient for legitimate professional services, if any one purpose of the emolument is to induce a prescription or sale of a drug, it is unlawful. *Id.*

104. The Patient Protection and Affordable Care Act, 42 U.S.C. §18001, was signed into law on March 23, 2010. The Affordable Care Act changed the language of the Anti-Kickback Statute to provide that claims submitted in violation of the Anti-Kickback Statute automatically constitute violations of the False Claims Act. 42 U.S.C. §1320a-7b(g). Further, the amended language of the Anti-Kickback Statute provides that to be found in violation of the statute "a person need not have actual knowledge . . . or specific intent to commit a violation".

105. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal healthcare programs, treble damages, civil monetary penalties and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

106. The 2003 OIG Guidance warns manufacturers that the provision of any service or any thing of value to a physician who might prescribe the manufacturer's products requires the manufacturer to evaluate whether it is providing a valuable, tangible benefit to the physician with any one purpose or intent (even if there are other legitimate purposes or intentions) to induce or reward referrals. More specifically, the 2003 OIG Guidance mandates the following:

a) That the manufacturer determine whether the provision of a service or a payment has the potential to interfere with, or skew, a physician's clinical decision-making process;

b) That the manufacturer determine whether the provision of a service or payment has the potential to undermine the clinical integrity of a formulary process;

c) That the manufacturer ensure that information provided to prescribers, decision-makers and/or patients is complete, accurate and not misleading;

d) That the manufacturer determine whether the provision of a service or payment has the potential to increase cost to federal health care programs, beneficiaries or enrollees;

e) That the manufacturer determine whether the arrangement or practice has the potential to be a disguised discount to circumvent the Medicaid Drug Rebate program best price calculation;

f) That the manufacturer determine whether the provision of the service or payment has the potential to increase the risk of over-utilization or inappropriate utilization of a product; and

g) That the manufacturer determine whether provision of the service or payment raises patient safety or quality of care concerns.

1) The Provision of Rebates Under the Anti-Kickback Statute

107. Most state Medicaid programs maintain formularies or preferred medication lists for the treatment of various conditions. It is extremely important for a drug manufacturer to be included on the formulary or preferred provider list for their products to be competitive and eligible for Medicaid prescription payments.

108. It is not uncommon for drug manufacturers to offer state Medicaid programs discounts or rebates to enhance their product's value and competitiveness within the market.

109. While the Anti-Kickback Statute allows for the provision of manufacturer discounts and rebates, they are only permitted under a specific exception or "safe harbor" to the statute. 42 U.S.C. §1320a-7b(b)(3)(A); 42 CFR §1001.952(h). In order to qualify for the safe harbor, any discount or rebate must be in the form of, or arise from, a reduction in the price of the good or service "based on an arm's length transaction." *Id.*

110. The *sine qua non* for manufacturer discount and rebate programs provided to drug purchasers under the Anti-Kickback Statute is "open and legitimate price competition in healthcare." 2003 OIG Guidance, p. 23735.

111. In addition, the discount or rebate must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale. Conditions for obtaining a rebate cannot be presented to a customer after the fact or on a *post hoc* basis.

2) OIG Opinions Providing Guidance on the Anti-Kickback Statute

112. In a special fraud alert issued in May of 1992, the OIG responded to an inquiry about whether a hospital offering free training for a physician's office staff in CPT coding or laboratory techniques violated the Anti-Kickback Statute. The OIG held that it did.

113. In an advisory opinion issued in October of 2006, the OIG responded to an inquiry regarding the propriety of a seller of durable medical equipment offering free reimbursement consulting services to some of its customers. The referenced "reimbursement consulting services" included: (1) general claims submission information, such as advice on how to code products; (2) how to review claims; (3) information on assistance in appealing denied claims; and (4) providing assistance related to medical justification for receiving particular products. *See* OIG-HHS, Adv. Op. No. 06-16 (issued October 3, 2006). The OIG found that these services constituted remuneration and violated the Anti-Kickback Statute.

114. The OIG further determined that the reimbursement consulting services at issue "would neither be limited in nature, nor free-standing," noting that the free services "would potentially confer substantial independent value upon the DME supplier." *Id.* at 5. The OIG also stated that any assistance "securing Federal reimbursement for individual beneficiaries to receive particular products could cause beneficiaries to receive greater quantities of, or more expensive" product than they actually required. *Id.* In addition, such reimbursement services would tend to provide a financial incentive to steer customers to purchase the supplier's products, "even if products from other manufacturers were less expensive or more appropriate."

115. In an additional advisory opinion, the OIG determined that any services, including pre-authorization services, that save a physician's office time, result in a realization of savings, or which were designed to refer or induce the purchase of a manufacturer's products could constitute unlawful remuneration and thus implicate the Anti-Kickback Statute. *See* OIG-HHS, Ad. Op. No. 10-04 (issued April 30, 2010).

b. Payment to TA's to Market Suboxone/Subutex Off Label

116. From 2006 until at least through 2013, Defendants knowingly, with reckless disregard and/or with deliberate ignorance of the truth violated the False Claims Act and Anti-

Kickback Statute, and caused false claims to be submitted to the Federal and State Payors identified herein, by designing and operating a program of paying their TA's to unlawfully promote Suboxone and Subutex. For most of the relevant time period between 2006 and the present date, Defendants retained far more TA's than it employed sales representatives. This intensive and unlawful use of TA's to market Suboxone and/or Subutex has played a critical role in achieving phenomenal sales volume.

117. The TA's were given cash payments to market Suboxone and Subutex to other physicians, state Medicaid agencies and government officials. The conduct of Drs. Wood, Lamb, Wollschlaeger and Sullivan, and others, as set forth in paragraphs above, provide examples of the fraudulent and unlawful purposes to which Defendants put TA's in the marketing of these drugs.

118. Defendants' TA's and sales representatives were given national training presentations and/or other documents by Reckitt that encouraged and sanctioned the prescription of Suboxone in dosages greater than 24 mg per day and/or for use in induction, during pregnancy and for treating pain. The Relator has personally observed some of these training materials, is in possession of some of them and has disclosed same to the United States and the states identified herein.

119. Defendants were well aware that the use of the TA's in this manner violated Federal regulations. Relator is in possession of a tape recording where Brandy Duso reported at Reckitt's National Meeting in April of 2013 that Richard Simpkin, President of Reckitt Benckiser Pharmaceuticals, acknowledged Defendants were out of compliance with the use of TA's. Defendants chose not to correct it until January 2014.

c. Unlawful Referrals from the "Here To Help" Program

120. From 2009 until at least through 2013, Defendants knowingly, with reckless disregard and/or with deliberate ignorance of the truth violated the False Claims Act and Anti-Kickback Statute, and caused false claims to be submitted to the Federal and State Payors identified herein, by designing and operating a program entitled "Here to Help" by which Defendants referred and continue to refer patients to physicians and provide valuable office assistance to physicians in exchange for the physicians prescribing Suboxone and Subutex.

121. The "Here to Help" program was fully funded and staffed by Defendants ostensibly to provide support to Suboxone and Subutex patients as part of a complete treatment plan that also included counseling but in actuality was implemented to increase Defendants' sales of Suboxone in light of the challenge from generics and branded products recently brought to market.

122. Defendants marketed the program to the physicians as a benefit to their practice. Defendants paid sales representative a separate bonus for the number of physicians that they successfully enrolled in the program.

123. Physicians would then be encouraged to enroll their patients in the program to receive counseling and encouragement to continue to use Suboxone and Subutex. In reality little counseling was achieved as the primary purpose of the program was to sell prescriptions.

124. Defendants marketed the program to physicians in such a manner as to highlight the benefits of the program to the physician's practice, to include : (1) receiving direct patient referrals from Defendants' program, (2) reducing their office staffing needs, and (3) improving profitability/efficiency for prescribing physicians by creating processes, policies and documents to alleviate their office workloads and overhead.

125. Documents supporting these allegations are attached hereto and incorporated herein as **Exhibit E** (Patient Focus Quality Care) and **Exhibit F** (Here to Help slide presentation to physicians). In one of the promotional slide presentations in **Exhibit F**, Dr. Gregory Dobash touted the benefits of the program and how he received a referral of a patient that was two hours away. Another physician relates how a care coordinator of the program "called in with the patient, stayed on the line to introduce the patient, then left the line." The patient subsequently made an appointment with the physician the following week.

126. Defendants knowingly, with reckless disregard and/or deliberate ignorance of the truth designed and marketed the program whereby in exchange for the physicians prescribing Suboxone and Subutex, the physicians would receive direct patient referrals, valuable benefits and office assistance. Such conduct violates the Anti-Kickback Statute and the False Claims Act and resulted in false and fraudulent claims being submitted to and paid by Federal and State Payors.

d. Unlawful Assistance in Promoting Suboxone/Subutex

127. From 2006 to present, Defendants' executives, sales representatives and TA's have knowingly, with deliberate indifference and/or deliberate ignorance of the truth violated the False Claims Act and Anti-Kickback Statute by designing and operating an unlawful marketing program to promote and assist physicians in starting their own Suboxone/Subutex clinics. Defendants unlawfully provided services, support and things of value to prescribing physicians in order to induce them to prescribe Suboxone and Subutex to their patients.

128. These kickbacks and things of value included advice, proprietary information, business information, consulting services, suggestions and support in establishing and growing Suboxone/Subutex based practices.

129. Defendants maintained NAABT as a surrogate marketing arm disguised as a not-for-profit patient advocacy group. NAABT provided valuable marketing services for the Defendants, including off-label marketing and providing unlawful referrals, all in violation of the False Claims Act and the parallel state statutes cited herein.

130. It was common for Defendants' employees to provide things of value to physicians in order to induce them to prescribe Suboxone and Subutex. Defendants' employees assisted physicians in setting up Suboxone and Subutex practices in order that they could be more profitable and efficient. This Relator was aware of the routine nature of this unlawful practice from conversations with TA's, sales representatives and executives and from documents instructing sales representatives to assist in this regard. In the winter of 2011, she personally witnessed one sales representative, Ana Farr, hand out documents to a physician with specific pricing, competitive and proprietary information in order to convince him to set up such a practice. Relator witnessed Farr taking information to prospective Suboxone physicians which showed that other physicians charged $150 cash for each visit. She showed these physicians how to do the cash office visit charges to make additional money and told them about other physicians who were also doing the same. Farr instructed the physician and office staff how to use Suboxone and how to induct with it. When questioned about what she had done, Farr told Relator that everyone in Reckitt was doing the same thing she was doing.

131. In 2013, Defendants' sales representatives were under pressure and required to sign up 16-18 physicians a year in order to receive the portion of the bonus related to increasing physician providers. Relator was also aware of other sales representatives marketing the cash pay model with Suboxone and Subutex in order to meet their 16-18 new physician quota. In West Virginia, sales representative Kathy McClain promoted Suboxone and Subutex by showing the

prospective Suboxone/Subutex physicians how much other physicians were making from patients paying in cash. She told the prospective physicians that other physicians were making between $300 to $500 per patient in cash a month for office visits, drug screens and higher dosage prescriptions. In Virginia, sales representative Dalphine Atkins was promoting the cash pay model by having prospective Suboxone/Subutex physicians shadow another established physician who already employed that system.

e. Unlawful Payments for State Formulary Exclusivity

132. Under the safe harbors found at 42 CFR §1001.952(h), a rebate provided by a drug manufacturer to a purchaser is lawful only if it is the result of open competition. 2003 OIG Guidance, p. 23735. In addition to the 2003 OIG Guidance, the safe harbor provision establishes a predicate requirement that the arrangement be the product of an "arms-length transaction." 42 CFR §1001.952(h)(5).

133. Beginning in early 2013, competitive products were placed on state formularies as alternatives to Suboxone film. Shortly after this occurred, Defendants restructured their bids to foreclose and prevent any competition with Suboxone film. They did this by threatening state Medicaid agencies with the elimination of rebates that the state agencies had enjoyed since the film went on formulary in September of 2010.

134. In July of 2015, Defendants informed officials of West Virginia Medicaid, including Brian Thompson, a drug utilization and review manager, that if Bunavail, a drug competitive to Suboxone, was placed on the West Virginia formulary, West Virginia would no longer receive the "supplemental rebate" that it had previously and routinely received from Defendants. Because of this threat, West Virginia Medicaid officials reversed an earlier decision made in April of 2015 to place Bunavail on their state formulary and left Suboxone as the only listed drug. Upon information and belief the same threats have been made and acceded to in

Virginia, Massachusetts, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Maryland, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Tennessee, Texas, Utah, Washington, Wisconsin and the District of Columbia.

135. Upon information and belief, Defendants have provided very significant and unlawful payments to gain exclusive positions on state Medicaid formularies in addition to West Virginia's. They have done so by communicating an express and open requirement to these states that in order for their Medicaid agencies to continue to receive substantial rebates, no other provider of similar or generic naloxone/buprenorphine pharmaceuticals may be placed on their respective formularies. Like West Virginia, states have acceded to Defendants' demand of exclusivity on state formularies because of Defendants' threat to end their rebate program.

136. By threatening to discontinue rebate programs in several states in the manner described above, Defendants have created a market environment in which open competition and arms-length transactions cannot occur. Their actions are antithetical to the goals of the Anti-Kickback Statute, the 2003 OIG Guidance, and 42 CFR §1001.952 to enhance and support free and open competition in an efficient and fair market. *See*, 2003 OIG Guidance, p. 23735; 42 CFR §1001.952(h)(5).

3) Marketing of Suboxone/ Subutex in Violation of DATA 2000

137. From 2004 until at least through 2013, in an effort to increase sales of Suboxone and Subutex, Defendants' executives, sales representatives and TA's knowingly, with deliberate indifference to and/or deliberate ignorance of the truth actively promoted and marketed Suboxone and Subutex in such a way as to encourage physicians to exceed the number of opioid addicted patients allowed under DATA 2000 and, more specifically, 21 U.S.C. §823(g).

138. Defendants maintained data on those physicians who prescribed to patients in excess of that allowed by Data 2000 and purposely continued to actively and unlawfully promote and market Suboxone and Subutex to those physicians. At times, sales representatives marketed Suboxone off label for pain in order to help support the physicians to circumvent the DATA 2000 patient limits. In Winter of 2013, Ray McIntyre, pharmacist for TennCare, reported to Relator the practice of physicians writing one prescription for the 8 mg limits and a second prescription for higher doses for pain.

139. In order to support the sales representatives' efforts to promote, target and encourage these physicians to exceed their 30 or 100 patient level, Defendants' employees were incentivized through the payment, based on volume, of SIP bonuses as previously discussed. Until 2011, sales bonus volumes were not capped at sales generated from those physicians who prescribed up to the lawfully permitted number of patients per physician, but allowed for, and paid on, patient volumes over and above the number of patients allowed to be treated under DATA 2000. When Relator complained about the SIP incentives, however, Defendants ceased the payment of bonuses for approximately a six month period on volumes over 100 patients. After subsequent complaints from the sales representatives, Defendants reinstated the bonus program. Since 2011, bonuses have been paid on the highest volume of a physician's patients up to 100 patients (not necessarily the first 100 allowed) plus a percentage of the total volume of all sales on the physician's patients.

140. As previously set forth, Defendants had the ability easily to determine if Suboxone/Subutex was being prescribed by physicians who had more than 100 patients and, in fact, Defendants maintained statistics on same. Despite being able to determine which physicians had a patient load greater than 100 patients and easily being able to exclude that

patient base and sales volume from the SIP bonus, Defendants intentionally ignored this information and included payment of bonuses based on sales volumes that were generated in violation of DATA 2000. These bonus systems generated substantial income to the sales representatives and substantial profits to Defendants. It is critical to note that virtually all bonuses paid to executives, directors and down to office staff employees of RBP and later Indivior were based on volume.

141. Defendants' executives, sales representatives, and TA's actively marketed Suboxone and Subutex to the following physicians, as well as many others, who were treating a number of opioid addicted patients in excess of the number permitted under 21 U.S.C. §823(g), and said marketing was done with knowledge of those facts:

PHYSICIANS	PRACTICE LOCATION
Herbert G.	Pennsylvania
Frank S.	Pennsylvania
William C.	Pennsylvania
David S.	Pennsylvania
Philip L.	Pennsylvania
Arthur D.	Pennsylvania
Mariano P.	Pennsylvania
Adid B.	Pennsylvania
Leo F.	Pennsylvania
Brian W.	Kentucky
Robin P.	Kentucky
Jerome D.	Kentucky
Robin P.	Kentucky
William C.	Kentucky
Christopher D.	Kentucky
William W.	Kentucky
Gary S.	Kentucky
Riley S.	Tennessee
Peter S.	Tennessee
Richard N.	Tennessee
John M.	Tennessee
Edgar O.	Tennessee
Robert G.	Tennessee
Micheal P.	Tennessee

Maria E.	Virginia

The full names and practice locations of the above physicians, as well as others, have been provided in Relator's disclosure of evidence.

4) Claims of False Superiority: Defendants Knowingly and Falsely Marketed Suboxone Film as Being Less Vulnerable to Diversion and Safer Than Suboxone Tablets

142. From the inception of the launch of Suboxone film until at least through 2013, Reckitt executives, sales representatives and TA's knowingly, with deliberate indifference and/or deliberate ignorance of the truth falsely promoted and marketed Suboxone film to Federal and State Payor officials and physicians as being less vulnerable to diversion and safer than Suboxone tablets. Many of these executives, sales representatives and TA's are identified in the paragraphs above. These false statements were made by Defendants' employees and TA's through oral and written communications as well as through handout marketing pieces.

143. Defendants' executives, sales representatives and TA's made numerous and material representations to state Medicaid officials that Suboxone film was less vulnerable to diversion, misuse and abuse than the tablets. Defendants' officials knew these representations were false when they were made. One example of these types of representations occurred shortly after Pierce Whites, a Kentucky Medicaid official, sent an email to James Sharp and Jessica Burke, both RBP executives, on April 18, 2013 and inquired as follows:

> As I understand it, you are making a public safety argument for the film based on diversion elimination and child proofing. We would like to see an argument showing that the short term savings on tablets is outweighed by the long term benefits of film. The argument against you is numbers based: the response should be too, at least in part. Diversion and child poisonings have costs, can you try to quantify those? Copy Senate staff as well, they seem receptive to your public safety argument and that is obviously critical.

144. Sharp responded to Whites' email as follows:

> Pierce,
>
> I can't thank you enough for the considerable time you shared with Karen, Patrick, Juan and I this morning and your willingness to find a way to encourage CoventryCare Managed Medicaid Plan to no longer pursue their current plan to force patients from the Suboxone Sublingual Film to the generic tablet. (A copy of CoventryCare's letter attached)
>
> . . . .
>
> To recap some of the key points I wrote down from today's meeting;
>
> • I wanted to start with the key advocates you thought we will need to work with going forward. In particular, we need to engage and develop best practices for MAT with PROP/Physicians for Responsible Opioid Prescribing, Kentucky ASAM and The Kentucky Board of Medical Licensure/KBML. ***We have a number of phenomenal clinical resources to contribute within our company and with Treatment Advocates/TA's who make up the best of the best local treatment providers that are role models for quality patient care.*** Each will be made available to these groups and to your offices as you require them. One of our company's guiding principles is to "Seek the Wisdom of the Team" and we look forward to our partnership with you and with them.
>
> . . . .
>
> • You also wanted to tap into any resource that would enable Kentucky to provide education on appropriate treatment and expand capacity to quality care. The first attachment is the Reckitt Benckiser Educational Grant Application. I was impressed by how much the state has already done to expand treatment capacity and would encourage you to work with the appropriate state association to apply for support for programming that will educate providers on the disease of opioid dependence and appropriate treatment with Suboxone Sublingual Film. Please have the interested association send their request to educationalgrants@rb.com. I believe that a full day summit can be developed as it has in Ohio to address this health and safety issue at the highest level and provide education to every key constituent that is engaged in providing a solution.

. . . .

• ***The subject of the use of Suboxone in pregnancy came up and as discussed this is an off label use for our product, so I recommended that you email me a request for this information from our Managed Care Medical Affairs Manager, Dr. Jane Ruby. Dr. Ruby can address any off label questions that you may have. Further, if you wish to have a more in depth perspective provided on the data we shared on unintentional pediatric exposures and the dire consequences attributed to the tablet version of our product, or the data supporting that there is clearly more diversion with the tablet versus our Suboxone Sublingual Film, don't hesitate to make that request as well as Jane is truly an expert on both topics.***

Finally and most importantly, you recommended that if the reasoning was sound, that a letter could be generated to the President of CoventryCares requesting that they reconsider their current plan to move patients in treatment with the ***safer Suboxone Sublingual Film to the generic tablets that can be crushed and inhaled and pose an increased risk of unintended pediatric exposure.***

Here are the salient points that should establish why this letter should be written as soon as possible and perhaps as you recommended that it gain appropriate media attention:

1. CoventryCares will be requiring KY Medicaid plan recipients to use a ***more divertible*** drug when they are already being treated with the ***safest product*** for them against their wishes. This is a disparity of treatment.

2. ***Moving patients to the generic increases the risk of diversion as the tablet can be crushed and inhaled,*** counter to what Congressman Rogers is fighting so passionately to eliminate with generics on Federal basis and which could increase the risk of relapse for many of those patients.

3. ***Tablets pose a measurably increased risk of unintentional pediatric exposure as loose tablets have shown to be attributed to all deaths of children to date[5] and over half of Medicaid recipients have children under the age of 6 which is the age group at greatest risk.*** A purely financial decision should not supersede the safety of even one child.

[5] As of this date, the experience with Suboxone was overwhelmingly with the pill form. The film had only recently been introduced.

> I thank you again for your time, considerable attention and guidance today and look forward to working closely with your office in any way that I may be of service.
>
> Regards,
>
> James Sharp
> State Government Manager-Midwest
> Phone: (616) 974-9580
> Reckitt Benckiser Pharmaceuticals, Inc.
> 10710 Midlothian Parkway, Suite 430
> Richmond, VA 23235
> www.suboxone.com
>
> (Emphasis added).

145. Sharp then wrote an email to Dr. Jane Ruby, Reckitt's Medical Affairs Director. In this email, which was sent on April 18, 2013, Sharp states as follows:

> Jane,
>
> I know you are off tomorrow, but here's the response I received from Pierce Whites, the gentleman who is general counsel to speaker of the house Stumbo.
>
> . . . .
>
> We need costs savings long term showing that the short term savings on tablets is outweighed by the long term benefits of film. Pierce is pretty specific in terms of far reaching costs like ER visits, neonatal costs associated with unintentional drug poisoning cost, etc. This big picture cost data will compel him to generate the letter to CoventryCare's president.[6]
>
> . . . .

146. These same claims of the false superiority of the film, and materially similar representations, were made by other of Defendants' sales representatives, executives and TA's. Defendants distributed **Exhibit G** to its TA's and prescribing physicians and asked them to send said correspondence to state Medicaid agencies. Many of them acceded in these requests. These

[6] CoventryCare is a contractor that provides support, advice and services to Kentucky Medicaid and Kentucky Medicaid patients.

letters falsely assert that Suboxone film is safer and less vulnerable to diversion than the Suboxone tablets. Defendants intentionally orchestrated this false and misleading campaign to achieve the unlawful objectives identified herein and to destroy competition and potential competition for the Suboxone brand. The false and misleading statements were material to the Federal Payors, State Payors and private insurers, all of whom relied on the veracity of the representations to their detriment. This caused a substantial delay in the market availability of generic Suboxone. This delay caused the Federal Payors, State Payors and private insurers significant damages.

147. When Relator questioned Defendants' practice of representing Suboxone film as less susceptible to pediatric exposure and injury, Jane Ruby sent her an email confirming that the U.S. Product Safety Commission had given the packaging of the tablet and film the same safety rating, effectively demonstrating the falsity of Sharp's representation to Kentucky Medicaid.

148. While Defendants were stating that the film was less divertible, they knew same was untrue at the time they developed the product. Dr. Edward Johnson, RBP's and later Indivior's V.P of Clinical, Scientific and Regulatory Compliance admitted to Relator privately, and to others in meetings, that the film was as easily divertible. Moreover, he knew and admitted to Relator in April 2012, at Reckitt's National meeting in California, that all that anyone needed to do to achieve the same high available in tablet form was to put the film on a spoon in water, heat the spoon, place the contents in a spray bottle or syringe, and then inhale it or inject it.

149. Defendants intentionally marketed the film as being less divertible and subject to abuse and represented to Federal and State Payors that they would have a system in which they would track prescriptions to help prevent abuse. In fact, Dr. Johnson advised Relator that the tracking program was never intended to be instituted. It never was instituted.

150. While Defendants stated that the film was safer, they knew this to be untrue at the time of marketing same. Dr. Johnson stated to Relator that the F2 packaging rating that Reckitt was touting as safer was the same as a child resistant prescription bottle of the type that Suboxone tablets and other tablets and pills were sold in.

151. The Defendants, in taking the actions set forth above, acted in concert with their TA's and other physicians to effect the false claims identified herein. The Defendants' collusion with its TA's and others caused much of the off-label marketing identified herein. The actions of Drs. Wood, Lamb, Wollschlaeger and Sullivan, identified above, among others, were the result of this of this collusion. In addition, Defendants colluded with NAABT to promote Suboxone as set forth above. Defendants further colluded with their TA's and other physicians by sending them letters, drafted by RBP (**Exhibit G**), to send to government officials, and which were, in fact, sent to government officials, falsely representing that Suboxone film was less divertible and safer than Suboxone or generic Suboxone in tablet form. All of these actions, and others identified in this Second Amended Complaint, constitute unlawful conspiracies in violation of the False Claims Act and the state statutes cited herein.

152. In committing the fraudulent acts and practices set forth in all preceding paragraphs herein, the Defendants:

1) knowingly presented, or caused to be presented, to an officer or employee of the United States government and the state and municipal governments identified herein false and fraudulent claims for payment and/or approval;

2) knowingly made, used or caused to be made or used, false records and/or statements to get a false or fraudulent claim paid or approved by the Federal and State Payors and agencies identified herein ;

3) conspired to defraud the Federal and State Payors by getting false or fraudulent claims allowed or paid; and

4) knowingly made, used or caused to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States government or state governments identified herein.

153. The vast majority of false claims related in this Second Amended Complaint were, in fact, paid by the Federal and State Payors identified herein. In paying the unlawful "kickbacks" and/or providing the things of value described herein to induce physicians and others to prescribe or purchase Suboxone and Subutex, the Defendants violated the respective Anti-Kickback statutes and False Claims Acts, or comparable statutes, of the federal government and the states identified herein.

154. In taking the actions set forth herein, the Defendants violated the Federal and State False Claims Acts identified herein, including 31 U.S.C. §3729, et seq.

COUNT 1

Violation of the Federal False Claims Act

"Off Label" Marketing Of Higher Suboxone and Subutex Dosages Than Those Lawfully Permitted By The FDA's Approved Packaging Insert

155. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

156. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth marketed, advertised for and encouraged physicians to prescribe Suboxone and Subutex in dosages not indicated or not otherwise approved for use by the FDA. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false and

fraudulent claims for the improper approval and payment of prescriptions for Suboxone and Subutex and used false and fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

157. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal and State Payors identified herein.

COUNT 2

Violation of the Federal False Claims Act

Marketing Suboxone and Subutex for the Off Label Uses of Induction and During Pregnancy

158. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

159. Defendants' sales representatives and TA's knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth promoted the "off label" use of Suboxone and Subutex for induction and during pregnancy, in both the film and tablet form, when no such indications were permitted within the Package Insert and no studies had been performed evaluating their efficacy for induction or use during pregnancy. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and Subutex and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

160. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal and State Payors identified herein.

COUNT 3

Violation of the Federal False Claims Act and Anti-Kickback Statute

Making Unlawful Kickback Payments to Treatment Advocates

161. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

162. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth violated the False Claims Act and Anti-Kickback Statute by designing and operating a program of paying their TA physicians to unlawfully prescribe Suboxone and Subutex, promote the writing of prescriptions of Suboxone and Subutex by other physicians, to assist in setting up other physicians' addiction practices and to market the drugs off label to those physicians. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and Subutex and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

163. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal and State Payors identified herein.

COUNT 4

Violation of the Federal False Claims Act and Anti-Kickback Statute

Providing Things and Services of Value to Physicians Through Defendants' Business Assistance Program and Through Their "Here to Help" Program

164. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

165. Defendants' sales representatives and TA's routinely distributed and provided physician pricing schedules, proprietary information, business information, consulting services, suggestions, support and free advice to physicians on how to start and grow Suboxone and Subutex practices. They knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth committed these acts in order to have the targeted physicians prescribe Suboxone and Subutex in large volume to their patients.

166. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth marketed, advertised for and encouraged physicians to prescribe Suboxone and Subutex by unlawfully providing referrals and other services and things of value through its "Here to Help" program to those physicians who prescribed Suboxone and Subutex.

167. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and Subutex and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

168. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal and State Payor programs identified herein.

COUNT 5

Violation of the Federal False Claims Act and Anti-Kickback Statute

Paying Kickbacks to State Medicaid Agencies to Obtain Exclusive Position on State Formularies

169. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

170. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth paid unlawful kickbacks to state Medicaid agencies the sole purpose of which was to destroy competition and to obtain exclusive positions on state formularies. This had the practical effect of eliminating or significantly reducing competition for Suboxone. These kickbacks violated the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b).

171. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

172. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal Payor and State Payor Programs identified herein.

COUNT 6

Violation of the Federal False Claims Act

Unlawful Marketing of Suboxone and Subutex to Physicians In Violation of DATA 2000 and for the "Off Label" Use of Pain Treatment

173. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

174. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth unlawfully marketed, advertised for and encouraged physicians to prescribe Suboxone and Subutex even when physicians were treating in excess of 30 patients in their first year of qualification under DATA 2000 and when they were treating in excess of 100 patients after their first year of qualification under DATA 2000.

175. In addition, Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth unlawfully marketed, advertised for and encouraged physicians to prescribe Suboxone and Subutex for the off label use of pain treatment in order to encourage and persuade physicians to circumvent the 30 and 100 patient limits set by DATA 2000 and to otherwise achieve larger sales volumes of Suboxone and Subutex.

176. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and Subutex and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

177. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal and State Payors identified herein.

COUNT 7

Violation of the Federal False Claims Act

Claims of False Superiority:
Unlawful Marketing to Physicians and Making False Statements to Federal and State Agencies Regarding Diversion and Safety to Promote Orders and Payment for Suboxone Film

178. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

179. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth, marketed, advertised for and encouraged physicians to prescribe, large volumes of Suboxone film by knowingly and falsely representing to these physicians that Suboxone film was less divertible than, and safer for patients, children and the public at large than, the tablet form of the drug. In doing so, Defendants knowingly caused to be presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

180. Defendants knowingly, with reckless disregard of the truth and/or deliberate ignorance of the truth marketed, advertised for and encouraged federal and state agencies to pay claims for Suboxone film submitted to them by knowingly and falsely representing to these agencies that Suboxone film was less divertible than, and safer for patients, children and the public at large than, the tablet form of the drug. In doing so, Defendants knowingly caused to be

presented to Federal and State Payors false or fraudulent claims for the improper approval and payment of prescriptions for Suboxone and used false or fraudulent records and documents to accomplish this purpose. The Federal and State Payors identified herein, unaware of the falsity and/or fraudulent nature of the claims caused to be presented by Defendants' conduct, paid for claims that otherwise would not have been allowed.

181. Defendants engaged in this conduct, knowing it to be unlawful, in an effort to destroy competition and potential competition for the Suboxone brand.

182. Defendants' conduct was the proximate and actual cause of more than $300 million in actual loss and damages to the Federal and State Payors identified herein.

COUNT 8

Violation of the Virginia Fraud Against Taxpayers Act

Va. Code Ann. §§ 8.01-216.1 to 8.01-219

183. All allegations set forth in this Complaint are incorporated into this Count as if fully set forth herein.

184. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

185. The Defendants violated the Virginia Fraud Against Taxpayers Act by: a) engaging in the off label marketing of higher Suboxone and Subutex dosages than those lawfully permitted; b) engaging in the off label marketing of Suboxone and Subutex for the purposes of induction and use during pregnancy; c) making unlawful kickback payments to TA's; d) providing unlawful kickbacks in the form of things and services of value to prescribing physicians and TA's; e) paying unlawful kickbacks to state Medicaid agencies to obtain exclusive positions on state formularies; f) marketing Suboxone and Subutex to physicians in